



MAR 13 2007

Food and Drug Administration
Rockville MD 20857
Re: ONYX LES
Docket No.: 2006E-0046

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,667,767, filed by Micro Therapeutics, Inc., under 35 U.S.C. § 156 *et seq.* We have reviewed the dates contained in the application and have determined the regulatory review period for ONYX LES, the medical device claimed by the patent.

The total length of the regulatory review period for ONYX LES is 1,682 days. Of this time, 825 days occurred during the testing phase and 857 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act involving this device became effective: December 14, 2000.

FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on December 14, 2000.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: March 18, 2003.

The applicant claims March 12, 2003, as the date the premarket approval application (PMA) ONYX LES (PMA P030004) was initially submitted. However, FDA records indicate that PMA P030004 was submitted on March 18, 2003.

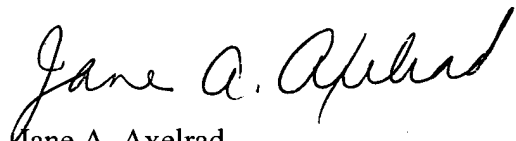
3. The date the application was approved: July 21, 2005.

FDA has verified the applicant's claim that PMA P030004 was approved on July 21, 2005.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in cursive script, reading "Jane A. Axelrad".

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Lorna L. Tanner
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